

## REMARKS

In the Office Action, claims 8 and 10 are rejected under 35 U.S.C. § 112, second paragraph; claims 1-34 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting; and claims 1-34 are rejected under 35 U.S.C. § 103. Claim 8 has been amended. Applicants believe that the rejections have been overcome or are improper in view of the amendments and for the reasons set forth below.

In the Office Action, claims 8 and 10 are rejected under 35 U.S.C. § 112, second paragraph. The Patent Office alleges that claim 8 is indefinite as the term “including” is used therein. Further, the Patent Office alleges that claim 10 is indefinite as it refers to natural seaweeds, natural sea gums, natural plant exudates, and natural fiber extracts.

With respect to the rejection of claim 8, Applicants have amended claim 8 as discussed above. Applicants note for the record that the changes to claim 8 were made for clarification purposes and thus not intended to narrow and/or disclaim any subject matter in view of same. Thus, Applicants believe that claim 8 as amended fully complies with 35 U.S.C. § 112, second paragraph.

With respect to the rejection of claim 10, Applicants believe that this rejection is improper. Indeed, the Patent Office even admits that the terms themselves are not indefinite. Further, Applicants believe that the scope and content of the claim terms at issue would be readily understood by one skilled in the art. Thus, claim 10 as pending fully complies with 35 U.S.C. § 112, second paragraph.

Accordingly, Applicants respectfully request that the rejection of claims 8 and 10 under 35 U.S.C. § 112, second paragraph be withdrawn.

In the Office Action, claims 1-34 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as allegedly being unpatentable over the claims of co-pending application No. 09/682,164. As this rejection has been provisionally made, Applicants respectfully submit that they plan to file a terminal disclaimer after a patent has been granted with respect to the co-pending application. Applicants believe that they have been responsive to this rejection as the rejection has been provisionally made.

In the Office Action, claims 1-34 are rejected under 35 U.S.C. § 103. More specifically, claims 1-34 are rejected in view of U.S. Patent No. 5,948,430 (“Zerbe”) and U.S. Patent No. 5,433,960 (“Meyers”); and claims 1-34 are rejected in view of U.S. Patent No. 4,777,046 of U.S.

Patent No. 4,777,046 (“*Iwakura*”) and *Meyers*. Applicants believe that the obviousness rejections are improper and thus should be withdrawn.

Of the pending claims, claims 1, 13, 20, 26 and 30 are the sole independent claims. Claim 1 recites a stand alone edible film for oral mucoadhesion that includes at least three types of film forming agents and not including pullulan. Claim 13 recites an edible film that includes a maltodextrin, a hydrocolloid and a bulk filler and not including a pullulan. Claim 20 recites an edible film including 5% to 60% by weight maltodextrin that has a dextrose equivalent of less than 20, a hydrocolloid and a bulk filler not including pullulan.

Claim 26 recites a method of producing an edible film for oral mucoadhesion. The method includes preparing a base solution that includes at least three types of film forming agents other than pullulan; and processing the base solution to form the edible film. Claim 30 recites a method of oral treatment. The method includes providing a food-grade film that includes at least three types of film forming agents and a medicament; orally consuming the food-grade film and releasing the medicament in an oral cavity.

Applicants have uniquely discovered that the use of a mixture of at least three types of film forming agents, such as maltodextrins, fillers and hydrocolloids, can be effectively utilized to prepare “stand alone” edible films. The edible films are composed of ingredients that are readily available, can be prepared at lower cost and display similar properties as compared to edible films composed of pullulan. In this regard, the edible films can provide a physiologically acceptable film which is suitably adapted to adhere to oral surfaces of an oral cavity and rapidly dissolve therein. See, Specification, page 3, line 28 to page 4, line 6.

The edible films of the present invention can be utilized to deliver or release oral care agent(s). Such agent(s) can include anti-microbial agents and salivary stimulants to treat, for example, halitosis, dental plaque, gingivitis, xerostomia, dry mouth, like oral conditions or combinations thereof. Further, the oral care edible film can act as a breath freshener against malodor. See, Specification, page 4, lines 7-11. Applicants have provided a number of examples illustrative of the claimed invention. See, Specification, pages 9-12.

In contrast, Applicants believe that the cited art, even if combinable, is deficient with respect to the claimed invention. The Patent Office primarily relies on the *Zerbe* and *Iwakura* references in support of the obviousness rejections. However, nowhere do these references, let alone their combinations thereof, disclose or suggest stand alone edible films that at least include

three film-forming agents and not including pullulan as required by the claimed invention. The primary focus of *Zerbe* relates to a composition that includes water-soluble polymers in combination with certain ingredients to provide a purported therapeutic and/or cosmetic effect. See, *Zerbe*, Abstract. The primary focus of *Iwakura* relates to a sheet-like preparation that includes a composition composed of a drug, gelatin or agar, gluten, carboxyvinyl polymer, a polyhydric alcohol, gum and wax as its essential components and a sheet-like support which purportedly acts to support the composition. See, *Iwakura*, Abstract. Yet, nowhere do either references specify that at least three film-forming agents are necessary to provide a “stand alone” edible film, let alone at least three film forming agents that include maltodextrins, fillers and hydrocolloids as further defined by the claimed invention. Indeed, both *Iwakura* and *Zerbe* are deficient with respect to a film-forming agent that includes maltodextrin as even admitted by the Patent Office. Thus, *Zerbe* and *Iwakura* are clearly deficient with respect to the claimed invention.

Further, Applicants do not believe that the Patent Office can rely solely on *Meyers* to remedy the deficiencies of *Zerbe* and *Iwakura*. At the outset, Applicants question whether *Meyers* can be combined with *Zerbe* and *Iwakura* in the first place. The primary focus of *Meyers* relates to coating a chewing gum composition with a film-forming agent in order to purportedly increase moisture stability of the chewing gum composition. See, *Meyers*, column 3, lines 23-28. As such, the Patent Office’s statement that *Meyers* teaches an “edible film composition” is clearly incorrect. Further, coating a chewing gum with a film-agent is much different from making an edible film composition itself which *Zerbe* and *Iwakura* purportedly disclose. In this regard, there is simply no motivation to combine these references. Indeed, the mere fact that references are combinable does not render the combination obvious unless the prior art suggests the desirability of the combination. See, *In re Mills*, 916 F.2d 680 (Fed. Cir. 1990). Thus, it is clear there is no such suggestion in *Meyers*, *Zerbe* or *Iwakura*.

*Meyers* also does not teach “film forming agents that include maltodextrin, bulking agents and plasticizers.” See, Office Action, page 3. Indeed, each item in the recited list of components is individually used as disclosed in *Meyers*, for example, in column 6 at lines 25-35. Moreover, the only disclosure concerning film-forming agents and plasticizers relates to HPMC and this is for the specific purpose of “improving the flexibility of the film.” See, *Meyers*, column 6, lines 54-55 and column 12, lines 36-38. Indeed, by its very nature, the chewing gum

compositions of *Meyers* are necessarily designed to be long lasting which is the exact opposite of the fast dissolving films of *Zerbe*. Therefore, Applicants submit that insofar as *Meyers* relates to coating chewing gum, it clearly constitutes non-analogous art, and thus is not properly combinable with the teachings of *Zerbe* (a fast dissolving film) or *Iwakura* (a sheet-like preparation for drug applications).

What the Patent Office has done is to rely on hindsight reasoning in support of the obviousness rejections. Of course, this is improper. As previously discussed, the primary *Zerbe* and *Iwakura* references are deficient with respect to a "stand alone" edible film that at least includes three film-forming agents, such as maltodextrin, as required by the claimed invention. Further, the clear emphasis of *Meyers* relates to chewing gum compositions and not "stand alone" edible films. Again, the claimed invention provides "stand alone" edible films that include at least three types of film forming agents other than pullulan, such as maltodextrins, fillers and hydrocolloids. Therefore, Applicants believe that one skilled in the art would not be inclined to modify the cited art to arrive at the claimed invention.

Based on at least these differences, Applicants believe that the cited art fails to disclose or suggest the claimed invention. Therefore, Applicants believe that the cited art, even if combinable, fails to render obvious the claimed invention.

Accordingly, Applicants respectfully request that the obviousness rejections be withdrawn.

For the foregoing reasons, Applicants respectfully submit that the present application is in condition for allowance and earnestly solicit reconsideration of same.

Respectfully submitted,

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